

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)	
COMPOUNDING PHARMACY, INC.)	MDL No. 2419
PRODUCTS LIABILITY LITIGATION)	Dkt. No. 1:13-md-2419-RWZ
_____)	
)	
This Document Relates to:)	
)	
Suits Naming the STOPNC Defendants)	
)	
)	

**OPPOSITION TO PSC’S MOTION TO STRIKE BILL MIXON, RPH’S
SUPPLMENTAL EXPERT REPORT [DOC. 2829]**

Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC (“STOPNC”); Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; and Vaughan Allen, MD (collectively “STOPNC Defendants”) respectfully submit this opposition to the PSC’s Motion to Strike Bill Mixon, RPH’s Supplemental Expert Report.

Introduction

Mr. Mixon’s supplemental report is entirely appropriate in substance and timing. The PSC’s motion contains significant and material omissions and mischaracterizes the content of Mr. Mixon’s reports. Mr. Mixon’s supplemental report is completely in line with his original report and his deposition testimony (a topic completely ignored by the PSC’s motion).

Sanctions are unwarranted. Service of Mr. Mixon’s supplemental report was justified (and required) by the supplementation obligations of FRCP 26(e)(2). And, the

PSC has failed to demonstrate any prejudice from the supplemental opinion that would warrant striking the supplement.

However, if the Court finds that some sanction is warranted, trial is still nearly four months away (and was well over five months away when the supplemental report was served). There is ample time for the PSC to conduct a second deposition of Mr. Mixon regarding this limited issue, a far more appropriate remedy.

Background

The PSC disclosed experts on December 15, 2015. On December 23, 2015, the STOPNC Defendants requested deposition dates for the PSC's experts.¹ The PSC refused to provide dates prior to serving its "reply" reports.² Thus, none of the Plaintiffs experts were deposed prior to service of the Defendants' expert reports. The PSC's first standard of care expert was deposed on February 29, 2016.³

The STOPNC Defendants timely disclosed Mr. Mixon as a common issue expert on January 15, 2016.⁴ Mr. Mixon's report plainly indicates that he intended to offer opinions on the appropriateness of purchasing from NECC and compounding pharmacies in general, from the standpoint of a compounding pharmacist.⁵

On March 17, 2016, counsel for the STOPNC Defendants informed the PSC that Mr. Mixon had reviewed additional materials in forming his opinions in the case.⁶ Included in the list of additional materials were Tenn. Code Ann. § 63-10-204 (2010),⁷

¹ See email attached as Exhibit 1.

² See email attached as Exhibit 2 (with relevant portion highlighted).

³ See deposition notice at Doc. 2645.

⁴ Report attached as Exhibit 3.

⁵ See Exhibit 3 at 14-15, 26-28.

⁶ Email attached as Exhibit 4 (with relevant portion highlighted).

⁷ Attached as Exhibit 5.

Tenn. Comp. R. & Regs. 1140-09-.01 (1999),⁸ and deposition testimony from Terry Grinder⁹ (three of the five items identified in Mr. Mixon's supplemental report), which the PSC contends establish the prescription requirement.

On March 22, 2016, Mr. Mixon was deposed by the PSC for just under seven hours. During his deposition, Mr. Mixon was questioned by the PSC about the use of patient-specific prescriptions.¹⁰ Mr. Mixon testified that, prior to the outbreak, he routinely dispensed medications to health care providers without patient-specific prescriptions (*i.e.*, for "office use").

On April 4, 2016 (prior to the common expert discovery deadline), the STOPNC Defendants received Mr. Mixon's deposition transcript.¹¹ The same day, after reviewing Mr. Mixon's testimony on the prescription issue, the STOPNC Defendants served Mr. Mixon's one-paragraph supplemental report, reiterating his deposition testimony that it was commonplace in 2011 and 2012 for compounding pharmacies to dispense medications without patient-specific prescriptions.¹²

Law and Argument

I. Mr. Mixon's supplemental report was appropriate in substance and timing.

A. Mr. Mixon's supplemental report does not contain a "new opinion."

Mr. Mixon's original report plainly stated that he intended to offer opinions regarding the appropriateness of STOPNC's purchase from NECC, from the perspective of a compounding pharmacist. The PSC concedes in its motion that the

⁸ Attached as Exhibit 6 (with relevant portions highlighted).

⁹ Attached as Exhibit 7.

¹⁰ See transcript excerpts from Mr. Mixon's deposition attached as Exhibit 8 (with relevant portions highlighted).

¹¹ Email enclosing transcript attached as Exhibit 9 (with original date received highlighted).

¹² Supplemental report attached as Exhibit 10.

patient-specific prescription requirement is inexorably intertwined in the appropriateness of the purchase decision.¹³

FRCP 26 contemplates that an expert will “supplement, elaborate upon, and explain his report in his oral testimony.” *Muldrow v. Re-Direct*, 493 F. 3d 160, 167 (D.C. Cir. 2007) (internal citations and quotations omitted). The PSC elected not to inform the Court that Mr. Mixon did just that during his deposition. He explained the difference between traditional (patient-specific) and office-use (nonpatient-specific) compounding.¹⁴ He testified that (1) it was lawful in North Carolina (where Mr. Mixon practices) to compound medications for office use (without prescriptions) prior to the outbreak,¹⁵ and (2) the North Carolina Board of Pharmacy eliminated office-use compounding after the fungal meningitis outbreak.¹⁶ Finally, Mr. Mixon testified that “it was routine to provide office-use compounding medications for doctors who treated pain [prior to the fungal meningitis outbreak].”¹⁷

Mr. Mixon’s one-paragraph supplemental report simply combines the opinions expressed in his original report (that it was appropriate to purchase medication from NECC) with the opinions elicited by the PSC at his deposition (that office-use compounding was acceptable prior to the outbreak). Thus, there was no “new opinion” in Mr. Mixon’s supplemental report. At most, it was a “refinement” of his previous opinions. *Maine Human Rights Comm’n v. Sunbury Primary Care, P.A.*, 770 F. Supp. 2d 370, 389 (D. Me. 2011) (internal citations omitted) (“[I]f a supplemental expert disclosure

¹³ Doc. 2830 at 5-6.

¹⁴ Mixon Dep. Tr., 56:13-57:4.

¹⁵ Mixon Dep. Tr., 121:6-122:3.

¹⁶ Mixon Dep. Tr., 94:1-12.

¹⁷ Mixon Dep. Tr., 122:8-17.

presents a new theory of the case, the district court has the discretion to exclude it and if it represents a refinement, the expert should be allowed to testify.”).

It is not even clear that supplementation was required in this instance. *C.f.* Fed. R. Civ. P. 26(e)(2) (supplementation required only when “information has not otherwise been made known to other parties during the discovery process”). The PSC was on notice of Mr. Mixon’s opinions on this issue based on his original report and deposition testimony. Likewise, the PSC had the opportunity to (and did) question him about these issues at his deposition. The STOPNC Defendants served a supplemental report out of an abundance of caution in order to cut off any claim from the PSC at trial that they were not on notice that Mr. Mixon intended to offer opinions on “office use” compounding, as he had at his deposition.

B. Mr. Mixon’s supplemental report was timely.

The STOPNC Defendants served Mr. Mixon’s supplemental report on April 4, 2016. The crux of the PSC’s motion is that Mr. Mixon’s supplemental report was served after the deadline for expert disclosures, which is true. The PSC ignores the fact that the supplement was served more than five months before trial and prior to the close of common expert discovery (April 7, 2016).

Moreover, the PSC completely ignores the supplementation obligations contained in FRCP 26(e). The rule not only contemplates but indeed specifically requires supplementation of expert reports and deposition testimony:

For an expert whose report must be disclosed under Rule 26(a)(2)(B), the party’s duty to supplement extends both to information included in the report and to information given during the expert’s deposition. **Any additions or changes** to this information must be disclosed by the time the party’s pretrial disclosures under Rule 26(a)(3) are due.

Fed. R. Civ. P. 26(e)(2) (emphasis supplied).

The PSC's motion would cut off that supplementation obligation at the deadline for expert witness disclosures, or perhaps after the expert witness's deposition, because any supplementation beyond that time would be subject to a motion to strike.¹⁸ But, the rule plainly contemplates that supplementation will continue up to the time for pretrial disclosures. See Fed. R. Civ. P. 26(a)(3)(B) ("Unless the court orders otherwise, these disclosures must be made at least 30 days before trial."). Accordingly, Mr. Mixon's supplemental report, served more than five months before trial, was certainly timely.

II. The sanction sought by the PSC (striking the supplemental report) is completely unwarranted.

As explained above, the STOPNC Defendants do not believe that any sanctions are warranted. Mr. Mixon's supplemental report was appropriately disclosed prior to the close of common expert discovery and more than five months before trial. However, if the Court agrees with the PSC's claim that Mr. Mixon's report needed to be supplemented sooner, sanctions are unwarranted because the timing of the disclosure was substantially justified and harmless. See Fed. R. Civ. P. 37(c)(1) (sanctions should not be imposed where the discovery infraction is substantially justified or harmless).

A. Service of Mr. Mixon's supplemental report after the Defendants' expert disclosure deadline but before the close of common expert discovery (and more than five months before trial) was justified.

Service of Mr. Mixon's supplemental report after the Defendants' disclosure deadline was substantially justified by (1) the testimony from other expert depositions

¹⁸ The PSC's motion position is ironic when viewed in the light of its recent expert disclosures from Gilbert Mathis. Mr. Mathis's original disclosure was little more than a letter stating that he intended to prepare a life care plan for Plaintiff Jane Wray (*the first trial case*), with a copy of his CV, and nothing else. Mr. Mathis's "supplemental" disclosure contained the actual life care plan and encompasses the entirety of the substance of Mr. Mathis's opinions. It was served after the Plaintiff's deadline for expert disclosures.

that occurred after the disclosure deadline and (2) the supplementation obligations of FRCP 26(e)(2).

* * * * *

Mr. Mixon's original report made clear that he intended to offer the opinion that, from the standpoint of a compounding pharmacist, it was appropriate for STOPNC to purchase from NECC. Admittedly, the original report did not specifically address prescriptions or office-use compounding. At the time of Mr. Mixon's disclosure, the PSC had disclosed its expert reports but had refused to present any of its witnesses for depositions.¹⁹ And, obviously, none of the Defendants' experts had been deposed at the time of the disclosure. Accordingly, it was unclear to what degree the PSC and its experts actually intended to emphasize the so-called "prescription requirement," as opposed to other theories.²⁰

As expert depositions progressed, the PSC's experts relied heavily on the purported prescription requirement at their depositions as the basis for their opinions.²¹ And, it became clear that the PSC intended to ask virtually every defense expert about their opinions on patient-specific prescriptions.²² As a result, Mr. Mixon reviewed the deposition testimony and Tennessee statutes the PSC claims contained the prescription requirement, prior to his deposition. The PSC makes much of the fact that these materials were available before Mr. Mixon's original report. However, the PSC elected

¹⁹ See Exhibit 2.

²⁰ The PSC alleged a host of problems with STOPNC's decision to purchase from NECC. See Master Compl. ¶¶ 151-206 [Doc. 545]. Mr. Mixon's original report addressed many of those issues. See Exhibit 3 at 26-28. The PSC and its expert's emphasis on the prescription issue did not fully reveal itself until expert depositions were underway.

²¹ See, e.g., transcript excerpt from PSC's expert James Gray, III, PharmD, attached as Exhibit 11.

²² See, e.g., transcript excerpt from Laura Thoma, PharmD attached as Exhibit 12. Like Mr. Mixon, Dr. Thoma was retained by the STOPNC Defendants to offer opinions regarding (1) errors in the compounding process and (2) the appropriateness of purchasing from NECC, from the perspective of a compounding pharmacist.

not to inform the Court that Mr. Mixon's review of these materials was disclosed to the PSC prior to his deposition and confirmed by the PSC at the deposition.²³ Furthermore, when questioned by the PSC about the prescription issue, Mr. Mixon testified, that it was "routine" to compound and dispense medication for office use without prescriptions.²⁴

Mr. Mixon's supplemental report reflects the reality that experts are "expected to react to duly admitted testimony to the extent it effects their expert opinions" and "apply their general opinions to evolving fact patterns." *Maine Human Rights Comm'n*, 770 F. Supp. 2d at 389. As expert depositions progressed, it became clear that the prescription issue is a cornerstone of the PSC's case. Thus, it became likely that Mr. Mixon would be called upon to offer opinions on this issue at trial (as he had at his deposition). To avoid any claim from the PSC that the Defendants violated their supplementation obligations under FRCP 26(e), the Defendants submitted a formal written supplement to Mr. Mixon's opinions the same day the Defendants received and had the opportunity to review Mr. Mixon's deposition transcript. *C.f.* Fed. R. Civ. P. 37(c)(1) (mandating exclusion of testimony where a party fails to timely supplement expert disclosures).

The testimony of other experts following Mr. Mixon's initial report, coupled with the supplementation requirement of FRCP 26(e) constitute "substantial justification" for the supplementation of Mr. Mixon's opinions after the disclosure deadline but prior to the close of common expert discovery. See Fed. R. Civ. P. 37(c)(1) (sanctions will not enter where failure to timely disclose was substantially justified). Therefore, no sanctions are warranted under FRCP 37.

²³ Mixon Dep. Tr., 24:8-25:6.

²⁴ Mixon Dep. Tr., 122:8-17.

B. The PSC has failed to demonstrate prejudice.

The delay in service of Mr. Mixon's supplemental report is harmless because (1) Mr. Mixon's review of materials on patient-specific prescriptions was disclosed to the PSC prior to Mr. Mixon's deposition, (2) the PSC had the opportunity to (and did) question Mr. Mixon regarding the prescriptions at his deposition, (3) the impending *Daubert* motion deadline has been vacated, and (4) the PSC was well-aware from other expert depositions that the Defendants' position is that prescriptions were unnecessary.²⁵

* * * * *

In deciding whether to exclude testimony, "the two most important factors to be considered are the prejudice and surprise suffered by the opposing party, and that party's ability to cure the prejudice." *Johnson v. H.K. Webster, Inc.*, 775 F.2d 1, 7, n. 7 (1st Cir. 1985). Here, there is no surprise or prejudice to the PSC.

Several days before Mr. Mixon's deposition, counsel for the STOPNC Defendants informed the PSC that Mr. Mixon had reviewed the following materials related to the prescription issue: Tenn. Code Ann. § 63-10-204 (2010), Tenn. Comp. R. & Regs. 1140-09-.01 (1999), and portions of the deposition testimony of Terry Grinder, DPH (pages 16-33).²⁶ At that point, the PSC was on notice that Mr. Mixon might render opinions on the issue.

²⁵ See transcript excerpt from Autry Parker, MD attached as Exhibit 13 (with relevant portion highlighted).

²⁶ See Exhibit 4.

Likewise, Mr. Mixon testified about dispensing medication without prescriptions more than once at his deposition:

- [T]raditional compounding is one preparation for one patient pursuant to a valid prescription, as opposed to, “office use compounding,” which is nonpatient specific.²⁷
- We started working with [one of the PSC’s experts] prior to the Drug Quality and Security Act.²⁸ That is when office-use compounding stopped, post-DQSA. Prior to that it was lawful in North Carolina to provide compounds that were for use in the office to diagnose, treat, mitigate, etc....But it’s pretty likely that we provided them compounded medications that were not pursuant to an individual prescription.²⁹
- [I]t was routine to provide office-use compounding for doctors who treated pain [prior to the outbreak].³⁰
- [The North Carolina Board of Pharmacy] eliminated office use compounding [after the outbreak].³¹

The PSC was apparently satisfied with its inquiry into the prescription issue at Mr. Mixon’s deposition because he was not even questioned about any of the materials he reviewed on that point, beyond confirming that he reviewed them.³² See *BASF Corp. v. Sublime Restorations, Inc.*, 880 F. Supp. 2d 205, 211 (D. Mass. 2012) (A “party can claim little prejudice” when it has already deposed an expert and the subsequent disclosure is unlikely to have changed the approach to the deposition.).

Any purported prejudice from Mr. Mixon’s supplemental report would have been cured if the PSC had done more than simply confirm that Mr. Mixon reviewed the materials regarding prescriptions, but the PSC elected not to do so. See *Johnson.*, 775 F.2d at 7, n. 7 (court must consider the prejudiced party’s ability to cure the prejudice).

²⁷ Mixon Dep. Tr., 56:13-57:4.

²⁸ The Drug Safety and Security Act was passed in 2013 (post outbreak).

²⁹ Mixon Dep. Tr., 121:6-122:3

³⁰ Mixon Dep. Tr., 122:8-123:9.

³¹ Mixon Dep. Tr., 94:1-12.

³² Mixon Dep. Tr., 24:8-25:6.

Additionally, one of the PSC's cited bases for prejudice, the impending *Daubert* motion deadline, is moot because the Court recently vacated the deadline.³³

Finally, the opinions in Mr. Mixon's supplemental report come as no surprise to the PSC because it is entirely consistent with the opinions expressed by the Defendants' other experts. This is not an instance where a supplemental disclosure puts forth an entirely "new theory." *Maine Human Rights Comm'n*, 770 F. Supp. 2d at 389. ("[I]f a supplemental expert disclosure presents a new theory of the case, the district court has the discretion to exclude it and if it represents a refinement, the expert should be allowed to testify.") Mr. Mixon's supplement says precisely what the Defendants' other experts have all stated: prescriptions were not required.

* * * * *

Given the absence of prejudice to the PSC, the Court should not impose any sanction for Mr. Mixon's supplemental report, and should certainly not impose the "severe" sanction of striking the report in its entirety. *Cruz-Vazquez v. Mennonite Gen. Hosp., Inc.*, 613 F.3d 54, 58, n. 1 (1st Cir. 2010) ("The procedure rule makes clear that in the absence of a harm to a party, a district court may not invoke the severe penalty provided for by Rule 37(c)(1).").

C. Even if the Court finds that sanctions are warranted, the appropriate remedy is to permit the PSC to take a limited deposition of Mr. Mixon regarding the opinions expressed in his supplemental report.

If the Court finds that (1) the supplemental report was untimely despite the requirements of FRCP 26(e) and (2) the delay was not "substantially justified" and (3) the Plaintiffs have been prejudiced, the appropriate remedy is not the "severe" sanction of excluding the testimony. The Court has the discretion to order a lesser sanction. See

³³ Doc. 2827.

Fed. R. Civ. P. 37(a)(1) (explicitly permitting the court to issue other sanctions instead of excluding the testimony).

Considering (1) the STOPNC Defendants' prompt action in supplementing Mr. Mixon's report upon receipt of the deposition transcript, (2) the PSC's choice not to ask Mr. Mixon any substantive questions about the materials reviewed regarding prescriptions prior to his deposition, and (3) that trial is still nearly four months away, the appropriate remedy is to permit the PSC a limited deposition on Mr. Mixon's one-paragraph supplemental report. The STOPNC Defendants should not be required to pay the costs or fees associated with the second deposition, as requested by the PSC,³⁴ because it is due, in part, to the PSC's failure to ask Mr. Mixon about the materials he reviewed regarding prescriptions at his first deposition.

Conclusion

The STOPNC Defendants respectfully request that the Court deny the PSC's motion in its entirety. Mr. Mixon's supplemental report was appropriate, timely, substantially justified, and did not result in any prejudice to the PSC.

If the Court is inclined to grant the motion, striking the report is not the appropriate remedy. At most, the PSC should be permitted to depose Mr. Mixon regarding the limited topics in his supplemental report, at the PSC's expense.

³⁴ See Doc. 2830, n. 14.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

C.J. Gideon, Jr.*

Chris J. Tardio*

Alan S. Bean**

Matthew H. Cline*

315 Deaderick Street, Suite

Nashville, TN 37238

Ph: (615) 254-0400

Fax: (615) 254-0459

chris@gideoncooper.com

***Attorneys for the Tennessee Clinic
Defendants***

* Admitted pursuant to MDL Order No. 1.

** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 3rd day of May, 2016.

/s/ Chris J. Tardio

Chris. J. Tardio